



U.S. Department of Justice

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July 1, 2011

Hon. George A. O'Toole
United States District Court
John Joseph Moakley
United States Courthouse
1 Courthouse Way
Boston, MA 02110

Re: *United States v. Stryker Biotech, LLC et al.*, 09-CR-10330-GAO

Dear Judge O'Toole:

We write to respond briefly to Defendants' June 29, 2011 letter, in which they urged the Court to dismiss, in part or in whole, Counts Six through Fourteen of the Indictment, charging conspiracy to violate the misbranding provisions of the Food, Drug and Cosmetic Act ("FDCA") (part of Count 6), and the substantive felony misbranding violations under the FDCA (Counts 7 through 14), in light of *Sorrell v. IMS Health, Inc.*, 564 U.S. ___, 2011 WL 2472796 (June 23, 2011).

IMS is irrelevant to this case. *IMS* addressed the question of whether Vermont could impose a specific content- and speaker-based burden on protected expression by preventing the sale and disclosure of pharmacy records that revealed prescribing practices of individual physicians to pharmaceutical manufacturers and their agents. The Vermont statute further sought to prevent the use of such physician prescribing information by pharmaceutical manufacturers in marketing their drugs to doctors. The Court specifically noted that Vermont "nowhere contends that its law will prevent false or misleading speech within the meaning of this Court's First Amendment precedents." 2011 WL 2472796, at 3. At heart, the Court noted that Vermont's interest in burdening detailer's speech "turns on nothing more than a difference of opinion." Id.

Nothing in this case remotely resembles the facts of the *IMS* case. These defendants are charged with mail fraud, conspiracy to defraud and to commit felony violations of the federal Food Drug and Cosmetic Act ("FDCA"), and substantive felony misbranding violations of the

FDCA which require the government to prove the defendants acted with the intent to "defraud or mislead." The grand jury charged that, by fraudulent means, these defendants misled physicians and others into using an untested, unapproved mixture of OP-1 and Calstrux that these doctors would not have otherwise used. These defendants misrepresented the nature of the FDA approval of OP-1, misleadingly caused physicians to assume OP-1 mixed with Calstrux was "just" OP-1, provided mixing recipes for OP-1 and Calstrux despite the facts that the mixture was never clinically tested and the FDA had not approved the safety or efficacy of the mixture, and concealed adverse events associated with the use of the mixture from physicians -- all after these defendants were explicitly trained that such conduct was criminal. Simply put, the "First Amendment does not shield fraud." Illinois ex rel. Madigan v. Telemarketing Associates, Inc., 538 U.S. 600, 612 (2003).

Respectfully submitted,

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By:

/s/ Gregory F. Noonan
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CERTIFICATE OF SERVICE

I hereby certify that a true copy of the above letter was served upon all counsel of record in this case by electronic service on July 1, 2011.

By: /s/ Gregory F. Noonan
Gregory F. Noonan
Assistant U.S. Attorney